

Part II.

Interview on August 12, 2010

1. The examiner indicated that SARS virus nucleic acid molecule of SEQ ID NO: 15 is free of the prior art. Claims 68, 69, 71, 73, 75, 77, 80, 81, 105, 107-109, 111, 113, 121, 122 and 131 contain allowable subject matter although the claim language needs to be perfected. The examiner further presented reasons why other claims are not allowable; see Para 2-5 below for details. The examiner offered the applicants' representative two alternatives: preceding (1) an allowance for the allowable claims; or (2) a final Office action to pursue all pending claims including rejections. Later that afternoon, after checking with the applicants, Attorney Leena Karttunen informed the examiner that Applicants would like to pursue allowable claims.

2. The examiner's reasons why Claims 70, 72, 77, 79, 106, 110-112, 114 and 134 are not allowable for the record:

3. First, the following claims would be objected to for informalities: Claims 79 and 122 would be objected to for some minor informality in claim language.

Claims 70, 72 and 113 would be objected to because they do not fall into the scope of the base claims. For example, the dependent claims 70 and 72, which are drawn to "said molecule comprises a sequence that is 99% identical to a sequence selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, and SEQ ID NO: 15 or a fragment thereof", are not within the scope of the base Claim 68, which requires a nucleic acid molecule of SEQ ID NO: 15. There is insufficient antecedent basis for the limitations of "SEQ ID NOs: 1-13, 16-18, 20-30, 90-159, 208, and 209 or a fragment thereof" of Claims 70, 71, 72 and 105 in either Claims 68 or 105.

Claim 114 is indefinite because it is not clear whether the "antisense" is intended to be complementary to the entire, or only a part of the SARS nucleotide sequence having SEQ ID NO: 15.

4. Secondly, newly added Claim 134 would be rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. Claim 134 is directed to a pharmaceutical composition comprising nucleic acid molecule SEQ ID NO: 15. "A pharmaceutical composition" indicates the composition is for medical application, requiring showing clinical benefit. However, the specification teaches that SEQ ID NO: 15 is the full genome of the SARS virus (Tor2 strain); see Para [0061] and Fig. 11A-K. In contrast to the claim, the specification teaches that a "SARS virus" is a virus putatively belonging to the coronavirus family and identified as the causative agent for sudden acute respiratory syndrome (SARS); see Para [0022]. It is known in the art that if a virus genome is introduced into a permissive cell or a suitable host, like a human, the virus genome can replicate and develop into an infective virus. Given that the nucleic acid SEQ ID NO: 15 is the whole genome of Tor2 isolated from SARS patient as described in the specification, it is expected that the nucleic acid SEQ ID NO: 15 can replicate in human, resulting in a SARS infection in human. The specification has not provided any teachings and guidance on how to use the whole genome of Tor2 having SEQ ID NO: 15 as a pharmaceutical composition for treating SARS infection in humans, resulting in clinical benefit, but without infecting humans with SARS. Therefore, the specification has not taught one of ordinary skill in the art how to use the claimed invention.

The new Claim 135 would be withdrawn as non-elected invention.

3. Third, the outstanding rejection of Claims 68, 69, 71, 73, 75, 77, 80, 81, 105, 107-109, 111, 113, 121, 122 and 131 under 35 USC 102(e) as being anticipated by Rota et al. (US 7,220,852 B1, effectively filed 25 April 2003), would be withdrawn in view of Applicants' Declaration under 37 CFR 1.131, submitted on April 28, 2010, and May 17, 2010. The declaration contains exhibits A, B, and C, which relate to activities of the inventors prior to April 23, 2003, and are said to show conception and reduction to practice of the complete genome sequence of SARS-CoV Tor2 isolate (see Exhibit B). The declaration states that Applicants continued to work diligently in this area, until filing of our provisional application. Thus, the Declaration is sufficient to overcome the rejection of 70, 72, 77, 79, 106, 110, 112 and 114, under 35 USC 102(e) as being anticipated by Rota et al.

The rejection of Claims 70, 72, 77, 79, 106, 110, 112 and 114 under 35 USC 102(e) as being anticipated by Rota et al. would also be withdrawn in view of the amendment to the claims. Claims 70, 72, 77, 79, 106, 110, 112 and 114 have been amended to be directed to SARS virus nucleic acids that are 99% identical to SEQ ID NO: 15. Rota does not teach this limitation. The rejection of 70, 72, 77, 79, 106, 110, 112 and 114 is therefore withdrawn.

4. Fourth, the outstanding rejection of Claims 68, 69, 80, 81, 111, 113, 121 and 122 under 35 USC 102(e) as being anticipated by Peiris et al. (US 7,547,512 B2, priority effective filing date: 24 March 2003 through 25 April 2003), would be withdrawn in view of Applicant's Declaration under 37 CFR 1.131 submitted on April 28, 2010, and May 17, 2010. The declaration has established conception and reduction to practice of the complete genome sequence of SARS-CoV Tor2 isolate prior to April 23, 2003 (see Exhibit B). Thus, the Declaration is sufficient to overcome the rejection of Claims 68, 69, 80, 81, 111, 113, 121 and 122 over Peiris et al.

However, the Declaration is insufficient to overcome the rejection of Claims 70, 72, 79, 110, 112 and 114 being anticipated by Peiris et al. for following reasons: Claims 70, 72, 79, 110, 112 and 114 have been amended to being directed to a genus of SARS virus nucleic acids, which are 99% identical to SEQ ID NO: 15. The scope of the claims

encompasses a genus of SARS viruses, which have up to about 300 nucleic acid variations of SEQ ID NO: 15 along the entire SARS genome of 29Kb. However, the Declaration states that Applicant had received one SARS virus isolate (Tor2 isolate), which lead to identification of its sequence of SEQ ID NO: 15. Applicants have not provided evidence showing that Applicants had reduced to practice of a genus of SARS viruses that are 99% identical to SEQ ID NO: 15. Peiris et al. teaches a SARS virus isolate, HKU-39849, whose genome nucleic acid, its complement thereof, and an antisense that is 99% identical to the instant SEQ ID NO: 15, as shown by Applicant's Exhibit C. Thus, the rejection of Claims 70, 72, 79, 110, 112 and 114 would be maintained and extended to Claim 106 necessitated by the amendment.

5. Finally, the outstanding rejection of Claims 68, 69, 73, 79-81, 110 and 113, under 35 USC 102(a), as being anticipated by Poutanen et al., would be withdrawn in view of the amendment to the claims. The claims have been amended to being drawn to a nucleic acids comprising SEQ ID NO: 15 (Full genome of Tor2). Poutanen teaches a fragment of SARS nucleic acid (GenBank accession number AY271716). In view of the amendment to the claims and Applicants' argument, the rejection of Claims 68, 69, 73, 79-81, 110 and 113 would be withdrawn. However, the rejection of Claims 70, 72, 111 and 112 over Poutanen et al., would be maintained for the reason forth below: The claims read on a fragment of SEQ ID NO: 15. Poutanen et al. teaches nucleic acid fragments, including primers and amplicons obtained by amplifying an isolated SARS virus. Poutanen discloses an amplicon (GenBank accession number AY271716) (see e.g. Para 1, right col. p. 2002), which has a sequence 100% identical to 15239 to 15396 of SEQ ID NO: 15. Furthermore, this fragment is 99% identical to a fragment 15239 to 15398 of SEQ ID NO: 15, for example. Since Poutanen's fragment meets the limitations of Claims 70, 72, 110, 111 and 121, the claims are anticipated by Poutanen.

In the Remarks, filed on April 28, 2010, Applicants argue that the sequence of AY271716 was not published in the Poutanen reference (on March 30th, 2003), but was submitted on April 8, 2003. In response to this argument, the Poutanen reference has disclosed the amplicon and GenBank accession number AY271716 on March 30, 2003. This teaching is sufficient to teach the limitation of "a fragment thereof" of the claims. The specific sequence of AY271716 is simply evidence of a fragment of SARS nucleic acid disclosed by Poutanen on March 30, 2003. It is also noted that both dates, both March 30, 2003, and April 8, 2003, are prior to the effective filing date of the instant application. Applicants' declaration does not provide statement and evidence showing conception and reduction to practice of the claimed invention prior to March 30, 2003. Therefore, Poutanen is proper prior art for the instant claims.

Interview on August 13, 2010

Attorney Leena Karttunen informed the examiner that Applicants would like to accept a new amendment to the claims, and authorized the examiner to enter the new amendment by an Examiner's Amendment.